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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/215,212 12/18/98 TEPPER

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001444 HM12/0410  
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EXAMINER

ANDRES, J

ART UNIT

PAPER NUMBER

1646

13

DATE MAILED:

04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/215,212

Applicant(s)

TEPPER ET AL.

Examiner

Janet L. Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: \_\_\_\_\_.

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### **RESPONSE TO AMENDMENT**

1. Applicant's amendment in paper no. 12, filed 24 January 2001, is acknowledged. Claims 1-28 are pending in this application. The text of those sections of Title 35, U.S. code, not included in this action can be found in a prior office action.

#### **Claim Rejections Withdrawn**

2. The rejection of claims 21 and 24 under 35 U.S.C. 102(b) as being anticipated by Cohen or Yeda is withdrawn in response to Applicant's arguments that neither reference teaches relevant pharmaceutical compositions.

3. The rejection of claims 12-14, 18-20, and 22 under 35 U.S.C. 102(b) as being anticipated by Yeda is withdrawn in response to Applicant's arguments.

4. The rejection of claims 21, 22, and 24 under 35 U.S.C. 102(b) as being anticipated by Novick is withdrawn in response to Applicant's arguments.

#### **Claim Rejections Maintained/New Grounds of Rejection**

5. The rejection of claims 10, 11, and 15-17 under 35 U.S.C. 102(b) as being anticipated by either Cohen or Yeda is maintained and applied to new claim 26.

5a. Applicant argues that neither Cohen nor Yeda teaches an isolated complex. This argument has been fully considered but has not been found persuasive. Amended claim 10 does not specify a degree of isolation; after immunoprecipitation or gel electrophoresis the complex would be isolated from at least some of the components of the original mixture.

5b. Applicant argues that 'consisting essentially of' does not include radioactive iodine because the definition on p. 32 excludes derivatization within the core sequence. This argument

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has been full considered but has not been found to be persuasive. The definition on p. 32 excludes substitutions, deletions, and additions, but does not exclude derivative.

6. The rejection of claims 10, 11, and 15-17 under 35 U.S.C. 102(b) as being anticipated by Novick is maintained. As stated above, the amendment to claim 10 does not specify a degree of isolation; affinity purification and gel electrophoresis do result in isolation of the complex from at least some of the components with which it was previously associated.

7. Applicant's arguments regarding the toxicity of the iodine-labelled complex are noted. However, while these arguments are relevant to the pharmaceutical compositions and the rejection of claims to such pharmaceutical compositions on this basis has been withdrawn. Claims 10, 11, and 15-17 do not require a pharmaceutical use, or any particular use, or exclude toxic embodiments. As Applicant states, the radiolabelled complex was produced for purposes of analysis and, as stated above, the means of analysis does result in a degree of isolation.

8. The rejection of claims 1-24 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "type I IFN biological activity" is maintained and newly applied to claims 25-28. Applicant's amendment limiting the claims to agonist activity is insufficient to limit the claims; absent any specific teachings as to what activities are considered to be "biological activity", limitation to positive activities does not exclude any activity, including unknown activity. The teachings on p. 33 refer to receptor agonist activity but are silent with respect to "biological agonist activity". Further, Applicant has not provided any evidence or arguments as to any art-standard usage of these terms.

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9. Claims 1-28 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "functional derivatives". Applicant has not described what actions are considered deriving and what actions are excluded.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov](mailto:yvonne.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


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Janet Andres, Ph.D.

April 9, 2001

  
YVONNE EVLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600